

Remarks

Claims 1, 2, 4-8, 10, 12, and 13 are pending in this application. Claim 3 is withdrawn from consideration as drawn to a non-elected species. Claims 5-7 have been canceled. Thus, claims 1, 2, 4, 8, 10, 12, and 13 are under consideration. Claim 1 is amended herein. Support for claim 1 as amended can be found at least in original claims 1 and 5-7. New claims 14 and 15 have been added. Support for claim 14 can be found at least in original claims 1, 5, and 7 and at least on page 10, lines 14-16. Support for new claim 15 can be found at least in original claims 1, 5, and 7 and throughout the specification.

35 U.S.C. § 103

Claims 1, 2, 4-8, 10, 12, and 13 are rejected under 35 U.S.C. § 103 (a) as allegedly being obvious over U.S. Patent No. 6,103,235 (the '235 patent). Applicants respectfully traverse this rejection. Included herewith is an Amendment and Petition to Correct Priority filed under 37 C.F.R. § 1.78(a). Applicants note that in the corrected priority claim, the present application claims priority to U.S. Serial No. 09/636,251 which is a continuation of and claims priority to U.S. Serial No. 08/439,409, now U.S. Patent No. 6,103,235. Thus the present application claims priority to the '235 patent. Therefore, the present application and the '235 patent have the same priority date and the '235 patent cannot render obvious the present invention. Support for the presence of the limitations of the claims can be found at least on page 10, line 6, where immunotoxins are described as being divalent, page 18, lines 17-25 where the administration of immunosuppressants including deoxyspergualin is discussed, page 20, lines 20-25 where the transplantation of pancreatic islet cells is discussed, and throughout the application where the administration of the immunotoxin is discussed and in original claim 1. In light of these facts, the present basis for rejection does not have merit, and its withdrawal is respectfully requested.

Claims 1, 2, 4-8, 10, 12, and 13 are rejected under 35 U.S.C. § 103 (a) as allegedly being obvious over WO 96/32137 in view of Henretta et al. (*Transplantation Proceedings* (1994) 26: 1138-1139). Applicants respectfully traverse this rejection. Applicants have herein made established a claim to priority to U.S. Serial No. 08/843,409, now U.S. Patent No. 6,103,235.

Support for this claim for priority is as described above. Therefore, Applicants have a priority date of at least April 15, 1997. The publication date of WO96/32137 is October 17, 1996, less than one year prior to the April 15, 1997 priority date. The subject matter of the WO96/32137 publication represents the work of the Applicants. Applicants submit herewith a declaration of Dr. Neville under 37 C.F.R. 1.132 establishing the WO96/32137 represents the Applicants' own work. Thus the WO96/32137 publication is not prior art and cannot render obvious the present invention. Applicants request withdrawal of the rejection, as the remaining cited references fails to teach each element of the claimed invention

U.S.C. § 112, first paragraph

Claims 1, 2-4, 8, 10, 12, and 13 are rejected under 35 U.S.C. § 112, ¶ 1, for allegedly lacking written description. In particular, the Examiner has rejected claims 1, 2, 4, 10, 12, and 13 for allegedly failing to provide written description "for a method employing an 'anti-CD3-diphtheria toxin immunotoxin.'" The Examiner concedes that written description does exist for "a divalent anti-T cell immunotoxin directed at the CD3 epitope further comprising a diphtheria toxin." As both the present claims and the embodiment for which the Examiner finds written description describe anti-CD3 diphtheria toxin immunotoxins, at issue is whether Applicants provide written description for immunotoxins other than divalent immunotoxins. Applicants have amended claim 1 to incorporate the limitations of original claim 5. Thus, applicants have amended claim 1 to recite, "administering to the diabetic subject a divalent anti-T cell diphtheria toxin immunotoxin directed at the CD3 epitope, thereby reducing the subject's T-cell population." Support for this amendment can be found at least in original claims 1 and 5-7. By this amendment applicants believe this objection has been overcome and respectfully request its withdrawal.

Applicants also respectfully point out that new claim 14 also has written description for the broader genus of an anti-CD3-diphtheria toxin immunotoxin. Contrary to the Examiner's position, written description for the broader genus of anti-CD3-diphtheria toxin immunotoxins can be found at least on page 10, lines 14-16 where both monovalent and divalent immunotoxins

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Application No. 09/810,999

are discussed. Additional support can be found throughout the specification where the immunotoxins are referred to as "anti-CD3 immunotoxins" not "divalent anti-T cell immunotoxins."

Pursuant to the above amendments and remarks, reconsideration and allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

Payment in the amount of \$2160.00 (\$1370.00 for a Petition to Correct a Priority Claim under 37 C.F.R. § 1.78(a) and \$790.00 for the large entity fee for a Request for Continued Examination) is enclosed. It is believed that no additional fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any additional amount or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

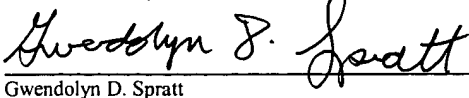


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12-06-04
Date